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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,943	03/19/2002	Kelvin G.M. Brockbank	110978	6307

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OLIFF & BERRIDGE, PLC  
P.O. BOX 19928  
ALEXANDRIA, VA 22320

EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

519

<b>Office Action Summary</b>	Application No. 10/099,943	Applicant(s) BROCKBANK ET AL.	
	Examiner Allison M. Ford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 19-20, drawn to a method of inhibiting growth of ice crystals, classified in class 252, subclass 70.
  - II. Claims 10-14, drawn to cryopreservation of a living system, classified in class 435, subclass 1.1.
  - III. Claims 15-19, drawn to a cryopreservation composition, classified in class 435, subclass 1.3.
  - IV. Claims 19-20, drawn to a method of inhibiting growth of ice crystals within a pipeline, classified in class 252, subclass 70.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and IV are independent inventions and thus are subject to restriction. The inventions are independent processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the method of Invention II requires the ice-controlling material to be present in a cryopreservation composition that further requires at least one additional cryoprotectant compound selected from the group listed in Claim 13, which is not required by any other group. The method of Invention I functions to inhibit growth of ice crystals on food products, which is not a function of the other

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methods. The method of Invention IV can use 1,3,5-cyclohexanetriol, by itself, as the ice controlling material; the other methods do not use 1,3,5-cyclohexanetriol.

Inventions I, III, and IV are also independent inventions and thus are subject to restriction. Inventions are independent if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The methods of Inventions I and IV do not require the ice-controlling material to contain an additional cryoprotectant compound selected from the group listed in Claim 17. Invention III includes the additional cryoprotectant compound, thus it is not usable in the methods of Inventions I and IV.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention II, the successful cryopreservation of living tissues, can be performed using known agents such as glycerol and DMSO.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent

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subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Claims 1,10, and 15 are generic to a plurality of disclosed patentably distinct species comprising 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexanedione, 1,4-cyclohexanedimethanol, a mixture of 1,4-cyclohexanediol with one or more of 1,3,5-cyclohexanetriol, 1,3-cyclohexanediol, 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexandione, and 1,4-cyclohexanedimethanol, charged derivatives of the ice-controlling materials that include one or more charged moieties therein, and polymers including one or more of the ice-controlling materials in the chain thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each claim, even though this requirement is traversed.

Further, Claim 5 is generic to a plurality of disclosed patentably distinct species comprising an ice crystal whose growth is to be prevented, a material within a pipeline, a food product, a living plant, a vehicle surface, a road surface or walkway, footwear, a light transmitter, a manufactured snow crystal, a utility line, and an organ, body fluid or other body tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Still further, Claims 13 and 17 are also generic to a plurality of disclosed patentably distinct species comprising acetamide, agarose, alginate, 1-analine, albumin, ammonium acetate, butanediol, chondroitin sulfate, chloroform, choline, dextrans,

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diethylene glycol, dimethyl acetamide, dimethyl formamide, dimethyl sulfoxide (DMSO), erythritol, ethanol, ethylene glycol, formamide, glucose, glycerol,  $\alpha$ -glycerophosphate, glycerol monoacetate, glycine, hydroxyethyl starch, inositol, lactose, magnesium chloride, magnesium sulfate, maltose, mannitol, mannose, methanol, methyl acetamide, methyl formamide, methyl ureas, phenol, pluronic polyols, polyethylene glycol, polyvinylpyrrolidone, proline, propylene glycol, pyridine N-oxide, ribose, serine, sodium bromide, sodium chloride, sodium iodide, sodium nitrate, sodium sulfate, sorbitol, sucrose, trehalose, triethylene glycol, trimethylamine acetate, urea, valine and xylose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each claim, even though this requirement is traversed.

Still further, Claim 19 is generic to a plurality of disclosed patentably distinct species comprising 1,3,5-cyclohexanetriol, 1,3-cyclohexanediol, 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexanedione, 1,4-cyclohexanedimethanol, a mixture of 1,4-cyclohexanediol with one or more of 1,3,5-cyclohexanetriol, 1,3-cyclohexanediol, 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexandione, and 1,4-cyclohexanedimethanol, charged derivatives of the ice-controlling materials that include one or more charged moieties therein, and polymers including one or more of the ice-controlling materials in the chain thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species for any of the generic claims are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

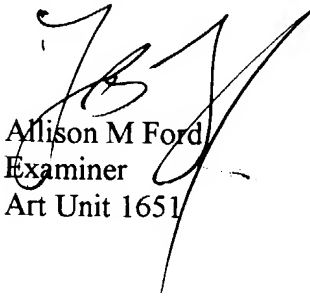
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Allison M Ford  
Examiner  
Art Unit 1651

AMF